

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0520986	(X3) Date Survey Completed 03/07/2023
Name of Provider or Supplier Madison Womens Clinic	Street Address, City, State 15 Madison Professional Park, Rexburg, ID	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on a direct observation, a review of laboratory procedures and an interview with the laboratory supervisor on 3/7/2023, the laboratory failed to ensure the safety of testing personnel from chemical, biochemical and biohazardous materials. The findings include: 1. During the laboratory tour on 3/7/2023 a direct observation identified a Coca-Cola and protein drink stored in the laboratory refrigerator used for reagent and quality control material storage. 2. A review of laboratory procedures identified that the laboratory failed to establish and follow a policy to ensure testing personnel safety from chemical, biochemical and biohazardous materials. 3. An interview with the laboratory supervisor on 3/7/2023 at 3:16 pm confirmed the above findings. 4. The laboratory reports performing 12,120 moderate and waived complexity tests annually.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
Based on a record review and an interview with the laboratory supervisor on 3/7/2023, the laboratory failed to document room temperature and humidity as required for operation of the Sysmex XP-300 while performing complete blood count (CBC) testing. The findings include: 1. A review of the Sysmex XP-300 manual identified an operational temperature of 15 C to 30 C and a relative humidity of 30% to 85%. 2. A review of the laboratory's temperature logs identified that the laboratory failed to document room temperature and humidity since the last inspection (6/8/2021). 3. An interview with the laboratory supervisor on 3/7/2023 at 3:12 pm confirmed that the laboratory fail to document room temperature and humidity. 4. The laboratory reports performing 10,000 CBC tests annually.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on a direct observation and an interview with the laboratory supervisor on 3/7/2023, the laboratory failed to discontinue the use of expired testing reagents. The findings include: 1. During the laboratory tour on 3/7/2023 a direct observation identified that the laboratory failed to discontinue the use of two expired OSOM BV Blue test kits, lot B2426 expiration 2/2020 and a bottle of McKesson normal saline lot 1711068 expiration 11/20/2019. 2. An interview with the laboratory supervisor on 3/7/2023 at 3:19 pm confirmed the above findings. 3. The laboratory reports performing 100 wet mount slide procedures and 2,020 waived tests annually.